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09/552,705	04/19/2000	Shiuan Chen	2124-311	4317

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EXAMINER

FRONDA, CHRISTIAN L

ART UNIT PAPER NUMBER

1652

DATE MAILED: 05/06/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No. 09/552,705	Applicant(s) Chen et al.
Examiner Christian L. Fronda	Art Unit 1652



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on \_\_\_\_\_  
2a)  This action is FINAL.      2b)  This action is non-final.  
3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

4)  Claim(s) 56-85 is/are pending in the application.  
4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5)  Claim(s) \_\_\_\_\_ is/are allowed.  
6)  Claim(s) 56-85 is/are rejected.  
7)  Claim(s) \_\_\_\_\_ is/are objected to.  
8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.  
10)  The drawing(s) filed on \_\_\_\_\_ is/are a)  accepted or b)  objected to by the Examiner.  
    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.  
    If approved, corrected drawings are required in reply to this Office action.  
12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All b)  Some\* c)  None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a)  The translation of the foreign language provisional application has been received.  
15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_  
4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_  
5)  Notice of Informal Patent Application (PTO-152)  
6)  Other: \_\_\_\_\_

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## DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 1/30/2003 (Paper No. 17) has been entered.

2. Claims 56-85 are under consideration in this Office Action.

### *Claim Rejections - 35 U.S.C. § 101*

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 56-85 are again rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible asserted utility or a well established utility.

Applicants' arguments filed 12/2/2002 (Paper No. 16) have been fully considered but they are not persuasive. Applicants' position is that the claims of the invention are not drawn to the disclosed nuclear receptor co-regulatory protein itself but to an assay method. The Examiner disagrees.

The specification does not specifically disclose the specific function of the nuclear receptor co-regulatory peptidic molecule that contains SEQ ID NOS: 5, 8, or 9 or its relationship to any disease. It is apparent that the specific function, biological activity, and utility is required in order to identify the pair of molecules that interact with the recited nuclear receptor co-regulatory peptidic molecule that contains SEQ ID NOS: 5, 8, or 9. It appears that the main utility of the protein is to carry out further research to identify the biological function and possible diseases associated with the nuclear receptor co-regulatory protein. Substantial utility defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utility. Thus, the claimed invention has no specific or substantial asserted utility.

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***Claim Rejections - 35 U.S.C. § 112, 1st Paragraph***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:  
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
6. Claims 56-85 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible asserted utility or a well established utility for the reasons set forth above in the rejection of claims 56-85 under 35 U.S.C. 101, one skilled in the art clearly would not know how to use the claimed invention.
7. Claims 56-85 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.  
The claims encompass any protein of any amino acid sequence which comprises SEQ ID NO: 5, 8, or 9. The specification discloses that PNRC (proline-rich nuclear receptor co-regulatory protein) has an amino acid sequence of 327 amino acid residues (SEQ ID NO: 8). The amino acid sequence of SEQ ID NO: 5 which consists of seven amino acid residues was identified as a binding motif in the disclosed PNRC having the amino acid sequence of SEQ ID NO: 8. The amino acid sequence of SEQ ID NO: 9 is disclosed as consisting of 23 amino acid residues which comprises SEQ ID NO: 5. However, the specification does not provide a written description of any protein comprising SEQ ID NO: 5, 8, or 9 because the specific amino acid sequence that is N-terminal and C-terminal to SEQ ID NO: 5, 8, or 9 has not been described. The specification does not provide any structural characteristics or properties for the protein other than comprising SEQ ID NO: 5, 8, or 9 for which no predictability of structure is apparent. Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

***Conclusion***

8. No claim is allowed.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. The fax phone number for this Group is (703)308-0294. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.

CLF



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